

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

ELMER HEISNER, Individually, and on)	
Behalf of JAYNE HEISNER)	
)	
Plaintiff,)	Case No.: 08 C 593
v.)	
)	Judge David H. Coar
GENZYME CORPORATION,)	
a Massachusetts Corporation)	Magistrate Judge Denlow
)	
Defendant.)	

PLAINTIFF, ELMER HEISNER'S, INDIVIDUALLY, AND ON BEHALF OF
JAYNE HEISNER, RESPONSE AND OPPOSITION TO DEFENDANT,
GENZYME'S, RULE 12 (b)(6) MOTION TO DISMISS PLAINTIFF'S
COMPLAINT

NOW COMES the Plaintiff, ELMER HEISNER, Individually, and on Behalf of the deceased, JAYNE HEISNER, (hereinafter “Plaintiff”) by and through his attorneys, THE LAW GROUP, LTD., and hereby respectfully requests that this Court deny Defendant’s, GENZYME’S, (hereinafter “Defendant”) Rule 12(b)(6) Motion to Dismiss the Complaint. In response to Defendant’s Rule 12(b)(6) Motion to Dismiss the Complaint, Plaintiff states as follows:

I. STATEMENT OF MATERIAL FACTS

On February 22, 2006, Jayne Heisner, an Illinois resident, died as a proximate result of the implantation of Seprafilm, an adhesion barrier, after undergoing surgery to remove an ovarian cyst on January 19, 2006. (See Plaintiff's Complaint, Paragraph No. 2). Seprafilm Adhesion Barrier was designed, manufactured and marketed by Genzyme, a Massachusetts corporation, and

approved by the United States Food and Drug Administration on December 20, 2000. (See Plaintiff's Complaint, Paragraph No. 5, 12).

II. STANDARD OF REVIEW UNDER FEDERAL RULE 12(b)(6)

A. Rule 12(b)(6)

Dismissal of an action under Federal Rule of Civil Procedure (F.R.C.P.) 12(b)(6) is only "warranted if the plaintiff can prove no set of facts in support of its claims that would entitle it to relief." *General Electric Capital Corporation v. Lease Resolution Corporation*, 128 F.3d 1074, 1080 (7th Cir. 1997); citing *Conley v. Gibson*, 355 U.S. 41, 45-4 (1957). Therefore, a 12(b)(6) motion should not be granted if the plaintiff demonstrates a set of facts entitled to relief. *Trump Hotels and Casino Resorts, Inc. V. Mirage Resorts, Inc.*, 140 F. 3d 478, 483 (3rd Cir. 1998).

B. Exception to Rule 12(b)(6) and Rule 56: Judicial Notice

F.R.C.P 12(b)(6) requires Courts to treat a motion to dismiss as one for summary judgment in the event they consider material outside the pleadings. *Loeb Industries, Inc. v. Sumitomo Corp.*, 306 F.3d 469, 479 (7th Cir. 2002). This is necessary because it provides each party with notice and the opportunity to submit affidavits and other evidence in opposing the summary judgment motion. *Id.* at 479; *Fleischfresser v. Directors of School Dist. 200*, 15 F.3d 680, 684 (7th Cir. 1994).

Defendant alleges that this Court should consider matters outside the pleadings without converting this motion to one for summary judgment, through

following a narrow exception to F.R.C.P. 12(b)(6) in which courts may take judicial notice of matters of public record. *General Electric Capital Corporation* 128 F.3d 1074, 1080- 1081 (7th Cir. 1997). This narrow exception only applies though when “an undisputed fact in the public record establishes that the plaintiff cannot satisfy the 12(b)(6) standard.” *Id.* at 1081. The Seventh Circuit in *General Electric* though cautioned “that judicial notice, therefore, merits the traditional caution it is given, and courts should strictly adhere to the criteria established by the Federal Rules of Evidence before taking judicial notice of pertinent facts.” *General Electric Capital Corporation* 128 F.3d 1074, 1081 (7th Cir. 1997); See also Fed.R.Evid. 201(b) advisory committee’s note. Furthermore, the Seventh Circuit found that taking judicial notice of disputable findings fails to comply with the Federal Rule of Evidence 201(b) indisputability requirement and will result in error. *General Electric Capital Corporation* 128 F.3d at 1082. (The 7th Circuit held in *General Electric Capital Corporation* that “courts generally cannot take notice of findings of fact from other proceedings for the truth asserted therein because these findings are disputable and usually disputed.” *Id.*).

Thus, in the case at bar, disputable findings exist concerning the Defendant’s compliance with the FDA’s Medical Device Amendments (MDA) and Premarket approval process in the manufacturing of their product, Seprafilm, and therefore this Court should not take judicial notice of these findings. *Id.* at 1080.

III. ARGUMENT

A. THE MEDICAL DEVICE AMMENDMENTS (MDA) FAILS TO PREEMPT PLAINTIFF'S STATUTORY AND COMMON LAW CLAIMS REGARDING COUNTS I, II, III, IV, V, VII

1. 21 U.S.C. § 360k and Pre-market Approval (PMA) Process of Medical Devices

The Medical Device Act Preemption Clause contains two subsections found in 21 U.S.C. § 360k which states as follows:

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement--

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

According to subsection b, the Secretary of Health and Human Services has the authority to allow the FDA to grant exemptions to state requirements.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 482 note 5 (1996).

According to 21 U.S.C. § 360e, Class III medical devices are required to undergo an approval of an application for premarket approval or if applicable an approval of a report seeking premarket approval. 21 U.S.C. § 360e(b),(c)(2). The FDA Premarket Approval Process (PMA) requires a manufacturer to provide the FDA with “reasonable assurance,” also known as the “premarket approval” or “PMA” process, that the device is both safe and effective. *See* 21 U.S.C. § 360e(d)(2); *Medtronic, Inc.*, 518 U.S. 470, 477 (1996). The Defendant alleges in their Motion to dismiss that once a manufacturer is approved through the PMA process, “a manufacturer may not make any changes...absent express permission from the FDA.” (See Defendant’s Motion to Dismiss, pg. 5). Defendant fails to acknowledge though that according to 21 CFR §§ 814.39(d)(1) and (2), the FDA permits manufacturers that have received PMA to make changes in labeling, quality control, and manufacturing which “‘enhance [] the safety of the device or the safety in the use of the device’ without prior FDA approval.” *Medtronic, Inc.*, 518 U.S. 470, 497 *citing* CFR §§ 814.39(d)(1) and (2) (1995). Furthermore, after the PMA, the manufacturers are subject to reporting requirements under § 360i which include the obligation to inform the FDA of new clinical investigation and studies “which the applicant knows of or reasonable should know of,” in accordance with 21 CFR § 814.84(b)(2), and to report incidents of death or serious injury. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1005 (2008). Therefore, contrary to Defendant’s allegations, manufacturers will be held accountable if they fail to inform the FDA of scientific studies or incidents of death or injuries that

would inhibit the FDA from reviewing and possibly withdrawing premarket approval based on this data. *Id.* at 1005; § 360e(e)(1); See also § 360h(e).

2. Plaintiff's Common Law and Statutory Claims Parallel the MDA Federal Requirements and Therefore Should Not be Preempted

Currently, 21 U.S.C. §360k(a) has been interpreted by the Supreme Court in *Medtronic, Inc. v. Lohr* of the U.S. to preempt state law requirements that are different from, or in addition to the federal requirements. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494-495 (1996). Therefore, the Supreme Court in *Medtronic* explained that state law requirements that “parallel” federal requirement are not preempted by 21 U.S.C. § 360k as follows:

“Nothing in §360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement...The presence of a damages remedy does not amount to the additional or different “requirement” that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing “requirements” under federal law.” *Medtronic, Inc.*, 518 U.S. 470, 495 (1996).

In *Medtronic, Inc.*, the U.S. Supreme Court held that State or local requirements that “are equal to, or substantially identical to, requirements imposed by or under the act,” are not preempted by §360k. *Id.* at 496-497; See also 21 CFR § 808.1(d)(2) (1995), § 808.5(b)(1)(i). Furthermore, the Supreme Court reaffirmed its holding in *Riegel v. Medtronic* in finding that “§360 does not prevent a State from providing a damages remedy for claims premised on a

violation of FDA regulations.” *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1001 (2008) (The Riegel Court though declined to address petitioner’s argument, that their lawsuit raised “parallel” claims that were not preempted by §360k, because it was not addressed previously in any of the lower courts).

Plaintiff’s Complaint claims that Defendant was strictly liable according to the Restatement (Second) of Torts; negligent in failing to use reasonable care in the marketing, selling, advertising, warning and distributing of Seprafilm; and impliedly warranted that Seprafilm was of merchantable quality safe and fit for use as an anti-adhesive. (See Plaintiff’s Complaint, Counts III, IV, VII). These common law claims parallel the federal premarket approval medical device safety requirements and Good Manufacturing Practice Requirements,¹ which specify the medical device regulations in regards to the manufacturing, designing, packaging, labeling, marketing, and distributing for medical devices. 21 C.F.R. § 820.1; 21 U.S.C. § 360e; § 360k; §360j(f).

Thus, according to *Riegel*, Plaintiff’s common law claims (strict liability; negligence; implied warranty) in the case at bar should not be preempted because they parallel the federal premarket approval safety requirements and Good Manufacturing Practice Requirements. See 21 CFR § 820.1, 820.5, 820.20, 820.25; 21 U.S.C. § 360e; § 360k; §360j(f). Therefore, Plaintiff’s common law claims do not challenge, according to the Defendant, nor impose any additional

¹ Good Manufacturing Practice requirements, which govern “the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. 21 C.F.R. § 820.1; 21 U.S.C. 360j(f).

nor different safety requirements than the ones previously approved under the PMA process by the FDA. *Id.*

In addition, on May 14, 2008, the House of Representatives Committee on Oversight and Government Reform chaired by Henry A. Waxman, 110th Congress, held a hearing² entitled “Should FDA Drug and Medical Device Regulation Bar State Liability Claims.” (See Committee on Oversight and Government Reform, <http://oversight.house.gov/story.asp?ID=1943>. The hearing examined the “implications of ‘preemption’ of state liability laws in the FDA context and whether FDA regulation of drugs and medical devices should bar injured patients from seeking compensation under state law”). Therefore in light of the Committee on Oversight and Government Reform’s Hearing and the potential passage of the Medical Devices Safety Act³, Defendant’s Motion to Dismiss is premature and Plaintiff’s Complaint should not be dismissed.

² Dr. Willaim Maisel, a cardiologist at Beth Israel Deaconess Medical Center and consultant to the FDA’s Center for Devices and Radiologic Health since 2003 stated in the Congressional hearing on May 14, 2008 that “I hope that by the conclusion of my brief comments today you will appreciate that FDA marketing clearance or approval of a medical product does not guarantee its safety...manufacturers’ responsibilities for product safety extend well beyond initial FDA approval and it is apparent that additional consumer safeguards are needed...During fiscal year 2006, 651 recall actions were initiated involving 1, 550 products-again reminding us that FDA product approval does not ensure device reliability and performance (See Testimony of William Maisel, Committee on Oversight and Government Reform, <http://oversight.house.gov/story.asp?ID=1943> (May 14, 2008); Center for Devices and Radiologic Health. CDRH FY 2006 highlights. Accessed May 12, 2008 at: <http://www.fda.gov/cdrh/annual/fy2006/fy2006.pdf>. In addition, Christine Ruther, a medical device engineer, stated that “FDA reviewers cannot know for certain that any particular device is safe and effective based on the data presented to it by the manufacturer before the device is on the market.” (See Testimony of Christine Ruther, Committee on Oversight and Government Reform, <http://oversight.house.gov/story.asp?ID=1943> (May 14, 2008).

³ The Medical Device Safety Act of 2008 cosponsored by U.S. Representatives Frank Pallone, Democrat from New Jersey, and Henry Waxman, Democrat from California, would amend the Federal Drug and Cosmetic Act by adding the subsection “No Effect on Liability Under State Law,” which states, “nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.” (See “Pallone and Waxman to Offer Preemption Amendment,” FDAnews Device Daily Bulletin, Vol. 5, No. 59 (March 25, 2008) found at: <http://www.fdanews.com/newsletter/article?articleId=105189&issueId=11428>; (See Testimony of the Honorable David Clark, Majority Leader, Utah House of Representatives, Standing Committee Chair,

3. Count V: Negligence Per Se

Plaintiff is entitled to relief on the basis of negligence *per se* and therefore Count V of Plaintiff's complaint should not be dismissed. A violation of a statute establishing a standard of care which proximately results in Plaintiff's injury illustrates evidence of negligence *per se* entitling the Plaintiff to relief. *Ney v. Yellow Cab Co.*, 117 N.E.2d 74; 2 Ill.2d 74 (Ill. 1954).

As Defendant alleges in their Motion to Dismiss, 21 CFR §360k fails to preempt claims "premised on a violation of FDA regulations if the state duties in such a case 'parallel,' rather than add to, federal requirements. *Riegel*, 128 S.Ct. at 1011. As stated previously, Section 21 U.S.C. §360k(a) specifically states:

"Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-(1) which is different from, or in addition to, any requirement applicable to the device under this chapter and(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

This Chapter referenced in §360k(a) refers to the Federal Food, Drug and Cosmetic Act codified at 21 U.S.C. §301 et seq. Therefore, Defendant is mistaken in their allegation that Plaintiff failed to plead the applicable statutory regulations in regards to Class III medical devices imposed by the FDA. While Plaintiff did not include the more specific medical device warnings defined by regulations 21 C.F.R. 801.1; 801.6, Plaintiff specifically stated in paragraph 43 of Plaintiff's Complaint that Defendant violated the Federal Food, Drug and

National Conference of State Legislatures, Committee on Oversight and Government Reform, <http://oversight.house.gov/story.asp?ID=1943> (May 14, 2008).

Cosmetic Act, 21 U.S.C. §301, et seq., related amendments and codes and federal regulations provided thereunder, which also codifies Defendants standard of care. (See Plaintiff's Complaint, Paragraph No. 43; 21 C.F.R. 801.1; 801.6). Plaintiff by amending his Complaint to include the more specific medical device warnings codified at 21 C.F.R. 801.1; 801.6 would remove doubt concerning Defendant's allegation that Plaintiff failed to state a cause of action. Furthermore, Plaintiff stated that Defendant's acts constituted an adulteration and or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331. (See Plaintiff's Complaint, Paragraph No. 45). The Medical Device Amendments codified at 21 U.S.C. §360, et seq., are part of the Federal Food, Drug and Cosmetic Act ("FDCA") codified at 21 U.S.C. §301, et seq., and therefore it is evident that Plaintiff included the proper statutory standards of care in the Complaint. (See Plaintiff's Complaint, Paragraph No. 43-47).

Furthermore, §360(e) is also part of the Federal Food, Drug and Cosmetic Act's and contains the FDA's premarket approval requirements and the requirements for withdrawing premarket approval. *See* 21 U.S.C. §360(e)(1)(A-D); §360(e). In determining whether to withdraw premarket approval, the Secretary reviews whether the "device is unsafe or ineffective under conditions of use prescribed, recommended, or suggested in the labeling thereof...the applicant has not complied with the requirements of this title...the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section

360j(f) of this title...the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular.” 21 U.S.C. §360(e)(1). Plaintiff stated specific violations of the statutory standards of care involving misbranding, adulteration, labeling, and warnings that are encompassed within the Federal Food, Drug and Cosmetic Act Class III requirements. 21 U.S.C. §360e.

In addition, section 21 U.S.C. §360j(f) entitled Good Manufacturing Practice Requirements states:

“the Secretary (1)(A) The Secretary may in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this chapter.” 21 U.S.C. §360j(f).

This section illustrates the statutory standard of care for medical devices intended for human use. It is clearly evident that Plaintiff claimed in the Complaint that Defendant failed to meet the standard of care set forth by the PMA of §360k and the Good Manufacturing Practice Requirements which proximately caused Plaintiff's injury and ultimate death.

Furthermore, Courts have found that §360k does not preempt claims for failure to comply with FDA statutes and regulations. *Mendes v. Medtronic, Inc.* 181 F.3d 13, 19-20 (1st Cir. 1994); *St. Jude Medical, Inc Silzone Heart Valves*, F. Supp.2d, 2004 WL 45503 (D. Minn., 2004) (Court held that “a claim for failure to comply with FDA regulations is not preempted because such a claim imposes

no additional or different requirements.”); See also *Mattingly v. Medtronic, Inc.*, 486 F.Supp.2d 964 (E.D. Mo., 2007) (Court found that the state law negligence per se claim imposed parallel similar requirements that was sufficient to withstand federal preemption); See also *Reiter v. Zimmer*, 830 F.Supp. 199, 204 (S.D.N.Y. 1993) (The Court found that MDA did not preempt negligence claim against manufacturer that violated FDA requirements). See also *Slater v. Optical Radiation Corporation*, 961 F.2d 1330, 1334 (7th Cir. 1992) (“scope of preemption under MDA ‘is limited to efforts by states to impose sanctions for compliance with federal regulations.’”)

As a result of Defendant’s breach of the Federal Food, Drug and Cosmetic Act standards of care as well as Defendant’s failure to adhere to the PMA mandated requirements regulating Seprafilm, Defendant negligence per se proximately caused Plaintiff’s injury. Therefore, Plaintiff’s Count V should not be dismissed.

B. Count VI: Breach of Express Warranty

To prevail on a claim for breach of express warranty, the “plaintiff may recover only after demonstrating that: (1) a warranty existed, (2) the defendant breached the warranty, and (3) that the breach was the proximate cause of the loss sustained.” *Gelormino v. J.C. Penney Co., Inc.*, 1997 WL 297601, *3 (Conn. Super. Ct. 1997) citing *Coates v. Rolscreen Co.*, Superior Court, judicial district of New Haven at New Haven, Docket No. 330146 (16 CONN.L.RPTR. 35, Jan 19, 1996). According to *Coates*, Plaintiff specifically identifies Defendant’s

express warranty in Count VI of their complaint. Plaintiff claimed Defendant expressly warranted to plaintiff factual allegations consisting of statements made by Defendant orally and in publications that Defendant's product was safe and proper for its intended use. (See Plaintiff's Complaint, Paragraphs No. 48-51). Furthermore, Plaintiff claims that the Defendant breached their express warranty due to the fact that Defendant's product was not safe and unfit for the anti-adhesive use for which it was intended. (See Plaintiff's Complaint, Paragraphs No. 48-51). Finally, Plaintiff claims that Defendant's failure to inform Plaintiff that Defendant's product was not safe and proper for its intended use was the proximate cause of Plaintiff's death from concrete intestines. (See Plaintiff's Complaint, Paragraphs No. 48-51). Therefore, Plaintiff specifically identified the purported express warranty and Defendant's breach of the express warranty in their complaint. (See Plaintiff's Complaint, Paragraphs No. 48-51).

In addition, the Supreme Court and U.S. Federal Courts have held that express warranty claims are not preempted by 21 U.S.C. §360k due to the fact they "arise from the representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law." *Richman v. W.L. Gore & Assocs., Inc.*, 881 F. Supp. 895, 904 (S.D.N.Y. 1995); See also *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525, 112 S. Ct. 2608, 2622 (1992) (The U.S. Supreme Court found that "a manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the 'requirement[s]' imposed by an express warranty

claim are not ‘imposed under State law,’ but rather imposed by the warrantor”). Thus, in accordance with the Supreme Court’s findings, Count VI should not be dismissed.

C. Defendant’s Duty to Warn Plaintiff

Contrary to Defendant’s assertions, Defendant does have a duty to warn Plaintiff of various risks associated with their medical device through the “learned intermediary” or health care professional and failure to warn the health-care professional does result in a breach of the standard of care. *Hansen v. Baxter Healthcare Corp.*, 198 Ill.2d 420, 438-439 (S.C. Ill. 2002). (The Supreme Court of Illinois held that under the “learned intermediary doctrine,” Baxter had a duty to warn “of the inherent dangers associated with friction-fit locks. “The Court went on to find “that the duty to warn was properly submitted to a jury”).

According to the Supreme Court of Illinois, medical device manufacturers have a duty to warn physicians of the device’s dangerous propensities. *Id.* Therefore, as a matter of law, a failure to warn the plaintiff through the “learned intermediary” does give rise to a cognizable claim according to *Hansen* and therefore the motion to dismiss as to all Counts should not be granted. *Hansen*, 198 Ill.2d 420 (S.C. Ill. 2002)

D. Plaintiff Withdraw Count II of Plaintiff’s Complaint

Plaintiff withdraws Count II of Plaintiff’s Complaint in regards to Defendant’s Violation of the General Laws of Massachusetts and respectfully

requests that this Court dismiss Count II without prejudice. (See Plaintiff's Complaint, Paragraphs 22-28).

E. Wrongful Death and Survival Statutes Should Prevail

Defendant mistakenly alleges that Plaintiff failed to plead correctly in accordance with the Illinois Wrongful Death Act, 740 ILCS 180/1, and the Illinois Survival Statute, 755 ILCS 5/27-6, in regards to punitive damages, which is incorrect. Contrary to Defendant's assertions that Plaintiff seeks punitive damages and other forms of relief not recognized by the act, Plaintiff in Prayer for Relief Paragraph No. 9 of the Complaint specifically claimed damages pursuant to the Illinois Wrongful Death Act codified at 740 ILCS 180/1. (See Plaintiff's Complaint, Paragraph No. 9, pg. 14); 740 ILCS 180/1. No where in Paragraph No. 9 in the Prayer for Relief does Plaintiff seek punitive damages for Plaintiff's wrongful death. *Id.*

Moreover, while Plaintiff's initial Complaint referenced the Illinois Survival Act through citing the survival provision of the Illinois Wrongful Death Act, Plaintiff seeks to amend its Complaint's Prayer for Relief to include damages for injuries caused to the deceased, Jayne Heisner, while she was alive, pursuant to Illinois's Survival Act, 755 ILCS 5/27-6. *See* 740 ILCS 180/2; 755 ILCS 5/27-6.

Furthermore, Defendant's allegations claiming that Plaintiff lacks the standing to file this claim are misstated. As Defendant stated in their Motion to Dismiss, an action under the Illinois Wrongful Death Act provision 180/2 "shall be brought by and in the names of the personal representatives of such deceased

person.” In addition, 740 ILCS 180/2 further states that “the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse.” 740 ILCS 180/2. Also, in the case of *Burgess v. Clairol, Inc.* the Northern District of Illinois held that “under the Illinois Wrongful Death Act, a decedent’s surviving spouse and next of kin have a cause of action for damages against the person who wrongfully caused the decedent’s death.” *Burgess v. Clairol, Inc.*, 776 F.Supp. 1278, 1280 (N.D. Ill., 1991). As Defendant notes, Plaintiff stated that he is the husband of the deceased, Jayne Heisner, and the personal representative. (See Plaintiff’s Complaint, Paragraph 56, pg. 13). Therefore, Plaintiff’s complaint correctly seeks relief under the Illinois wrongful death and survival act for the death of Plaintiff’s wife, Jayne Heisner, and thus should not be dismissed.

CONCLUSION

WHEREFORE, Plaintiff, ELMER HEISNER, Individually and on Behalf of JAYNE HEISNER, respectfully requests that this Court deny Defendant's Rule 12(b)(6) Motion to Dismiss on Counts I, III, IV, V, VI and VII of Plaintiff's Complaint and dismiss Count II of Plaintiff's Complaint without Prejudice.

Respectfully Submitted,

By: /s/ Kurt D. Hyzy
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CERTIFICATE OF SERVICE

I do hereby certify that, on this 16th day of May, 2008, a true and correct copy of **Plaintiff, Elmer Heisner's, Individually, and on Behalf of Jayne Heisner, Response and Opposition to Defendant, Genzyme's, Rule 12(b)(6) Motion to Dismiss Plaintiff's Complaint** were served electronically upon the following individual:

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